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The White House

Office of the Press Secretary

For Immediate Release January 28, 2016

Memorandum -- White House Cancer Moonshot Task Force

January 28, 2016

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: White House Cancer Moonshot Task Force

Cancer is a leading cause of death, and cancer incidence is expected to increase worldwide in the coming decades. But today, cancer research is on the cusp of major breakthroughs. It is of critical national importance that we accelerate progress towards prevention, treatment, and a cure -- to double the rate of progress in the fight against cancer -- and put ourselves on a path

to achieve in just 5 years research and treatment gains that otherwise might take a decade or more. To that end, I hereby direct the following:

Section 1. White House Cancer Moonshot Task Force. There is established, within the Office of the Vice President, a White House Cancer Moonshot Task Force (Task Force), which will focus on making the most of Federal investments, targeted incentives, private sector efforts from industry and philanthropy, patient engagement initiatives, and other mechanisms to support cancer research and enable progress in treatment and care. The Vice President shall serve as Chair of the Task Force.

(a) Membership of the Task Force. In addition to the Vice President, the Task Force shall consist of the heads of the executive branch departments, agencies, and offices listed below:

(i) the Department of Defense;

(ii) the Department of Commerce;

(iii) the Department of Health and Human Services;

(iv) the Department of Energy;

(v) the Department of Veterans Affairs;

(vi) the Office of Management and Budget;

(vii) the National Economic Council;

(viii) the Domestic Policy Council;

(ix) the Office of Science and Technology Policy;

(x) the Food and Drug Administration;

(xi) the National Cancer Institute (NCI);

(xii) the National Institutes of Health (NIH);

(xiii) the National Science Foundation; and

(xiv) such other executive branch departments, agencies, or offices as the President may designate.

A member of the Task Force may designate, to perform the Task Force functions of the member, any person who is a part of the member's department, agency, or office, and who is a full time officer or employee of the Federal Government. At the direction of the Chair, the Task Force may establish subgroups consisting exclusively of Task Force members or their designees under this section, as appropriate.

(b) Administration of the Task Force. The NIH shall provide funding and administrative support for the Task Force to the extent permitted by law and within existing appropriations.

The Vice President shall designate an officer or employee of the executive branch as the Executive Director of the Task Force, who shall coordinate the work of the Task Force.

Sec. 2. Mission and Functions of the Task Force. The Task Force shall work with a wide array of executive departments and agencies that have responsibility for key issues related to basic, translational, and clinical research, therapy development, regulation of medical products, and medical care related to cancer. Consistent with applicable law, the Task Force also will consult with external experts from relevant scientific sectors, including the Presidentially appointed National Cancer Advisory Board (NCAB). The NCAB shall advise the Director of NCI on its recommendations respecting the future direction and program and policy emphasis of NCI as it relates to the work of the Task Force. To assist the NCAB in providing this advice, the NCAB is strongly encouraged to establish a working group consisting of a Blue Ribbon Panel of scientific experts. The Director shall relay the advice of the NCAB to the Task Force, as appropriate. The functions of the Task Force are advisory only and shall include, but shall not be limited to, producing a detailed set of findings and recommendations to:

(a) accelerate our understanding of cancer, and its prevention, early detection, treatment, and cure;

(b) improve patient access and care;

(c) support greater access to new research, data, and computational capabilities;

(d) encourage development of cancer treatments;

(e) identify and address any unnecessary regulatory barriers and consider ways to expedite administrative reforms;

(f) ensure optimal investment of Federal resources; and

(g) identify opportunities to develop public-private partnerships and increase coordination of the Federal Government's efforts with the private sector, as appropriate.

Sec. 3. Outreach. Consistent with the objectives set out in section 2 of this memorandum, the Task Force, in accordance with applicable law, in addition to regular meetings, shall conduct outreach with representatives of the cancer patient community, academia, business, nonprofit organizations, State and local government agencies, the research community, and other interested persons that will assist with the Task Force's development of a detailed set of recommendations.

Sec. 4. Transparency and Reports. The Task Force shall facilitate the posting on the Internet of reports and engage in an open, reciprocal dialogue with the American people. The Task Force shall present to the President a report before December 31, 2016, on its findings and recommendations, which shall be made available to the public and posted on the Internet.

Sec. 5. General Provisions. (a) The heads of executive departments and agencies shall assist and provide information to the Task Force, consistent with applicable law, as may be necessary to carry out the functions of the Task Force. Each executive department and agency shall bear its own expense for participating in the Task Force.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 6. Publication. The Secretary of Health and Human Services is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

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The Moon Shot: A National Immunotherapy Initiative for the Conquest of Cancer

The Cancer QUILT Coalition to Develop a Cancer Vaccine for N=1

Background: In his seminal report on the "Cancer Crusade" Richard A. Rettig states, "*The large issue that divided people the most had to do with how scientific research be supported to improve the health of the American public most effectively and rapidly? On this key issue there was and is today an underlying, unresolved conflict*". This issue stated in 1977 still remains today almost 40 years later.

There are unique times when events and advances in technologies converge to elicit a quantum leap in progress. That time is now for the rapid exploitation of immunotherapy for the benefit of millions of cancer patients. The cloning of the human genome has led to an enormous knowledge base as to how cancers are initiated and progress. Over the last several years scientists studying the cancer process have elucidated the fact that the vast majority of cancers arise and progress due to numerous mutations in cancer cells. Moreover, for the most part, each patient's cancer is unique in terms of the nature and number of mutations. It has now been realized that this is one of the major reasons why many existing therapeutic regimens designed to target a single or even a few mutations have had limited success to date.

The Age of Immunotherapy in Cancer: The human immune system has evolved over the millennia to combat an enormous range of invasive entities, such as viruses and bacteria; indeed, the immense diversity of the healthy, intact human immune system is believed to be responsible for eliminating many potentially cancerous cells that arise during a lifetime. This is evidenced by studies that have shown that individuals with impaired immune systems, such as long term AIDS patients, will develop more cancers than individuals with a normal immune system. It is this unique diversity and the remarkable ability to survey and eliminate harmful entities that defines the human immune system, which can be exploited to combat the individual mutations reflected in so-called neo-antigens in tumor cells. The potential thus now exists to develop immunotherapies tailored to the unique tumor signature of individual patients.

Enhanced understanding of how individual components of the immune system function and new findings in cancer cell biology have now merged to drive the development of new immunotherapy approaches to combat cancer. In the last few years several of these immunotherapies have been approved by the FDA for the treatment of patients with some forms of lung cancer, melanoma, and prostate cancer. But this benefits only a fraction of cancer patients and much more progress in this area must be made.

A paradigm shift in cancer care from highly toxic, high dose chemotherapy to considerably less toxic immunotherapy is upon us. This is significant since combinations of low dose chemotherapy, radiotherapy and immunotherapeutics can be used with fewer compounding toxicities and thus provide a better quality of life for the cancer patient. A major point of emphasis, moreover, is that each type of cancer immunotherapy appears to activate a different

component of the immune system and when used in combination, is more effective. To date, there are literally dozens of novel cancer immunotherapeutic agents in active clinical studies.

The Obstacles: One of the major challenges now facing rapid progress in this field is that numerous pharmaceutical and biotech companies each have their own immunotherapeutic agents in the form of antibodies, immune cells, and vaccines in preclinical and clinical studies. Taken together with the enormous heterogeneity and antigenic profiles of individual patients cancer cell, it is a challenge at this time to define which of these numerous agents, when used in combinations, will prove optimal for each type and stage of cancer. Progress is clearly not moving as rapidly as possible due to the development in silos of many of these agents, and the lack of a coordinated combinatorial development effort.

For this reason we are proposing a **National Immunotherapy Initiative** to collectively undertake a **QUILT** (**QU**antitative, **I**ntegrative, **L**ifelong, **T**rial) in patients with cancer to develop an immunotherapy approach designed ultimately as a vaccine for N=1. This QUILT trial will be implemented by a QUILT Coalition where the National Cancer Institute, big pharma, biotech companies and private foundations can pool resources and the agents they have developed to more rapidly define which new immunotherapeutics and combinations of immunotherapies will most benefit patients with various cancer types and stages; and where regulatory agencies such as the FDA can provide guidance for combinations of innovative agents amongst these various entities; and where insurance companies and self insured payors can gain insight into outcomes and cost to reimburse for value;

Potential members of this coalition to launch the National Immunotherapy Initiative have gathered to discuss obstacles that may impede the successful moon shot for cancer and the goal of *establishing an effective vaccine immunotherapy treatment for this disease in 5 years rather than a decade*.

The Proposal: A union of forces to successfully implement the opportunity of combinatorial immunotherapies in the war against cancer. The goal is to obtain a commitment by members of the QUILT Coalition to collectively address the obstacles that may impede rapid clinical implementation of the National Immunotherapy Initiative.
The issues needing to be addressed are:

1. **Validation of Big Science:** Complex science involving the human immune system and the validation of the safety and efficacy of combination therapy must be tested by reputable scientific enterprises in an unbiased manner without any prejudices other than the interest of the patient.

2. **Access to novel agents and approved drugs**: One of the major challenges facing rapid progress in this field is that numerous pharmaceutical and biotech companies each have their own immunotherapeutic agents in the form of antibodies, immune cells, and vaccines in preclinical and clinical studies.

3. **FDA Regulation:** Novel approaches for the adaptive combination of novel agents in this new paradigm where the combined multi-agents serves as a systems biological approach to the treatment of cancer are needed.

4. **Care coordination** and real-time monitoring of safety and outcomes with integration of complex molecular data, phenotypic data obtained from disparate electronic records are needed.

5. **Ability to measure outcomes and cost** in real time to enable payors to pay for value rather than procedures.

6. **Network Infrastructure:** Highly Secure Bandwidth to Transmit Big Data & Interrogate complex molecular information in large scale

The QUILT Coalition will address each of these problems by bringing together stakeholders each of whom have the ability to solve these interdependent obstacles within their own sphere of activity and authority.

1. **Validation of Big Science:** The NCI and major academic cancer centers will collectively address the unbiased clinical validation of the science.

2. **Access to novel agents and approved drugs:** Biotech and big pharma should commit to make available their approved drugs and drug pipeline to be tested in combination trials by credible unbiased organizations such as the NCI.

3. **FDA Regulation:** The FDA should commit to adopting innovative, adaptive, clinical trials allowing combination of innovative agents to test the biological system in the era of precision medicine

4. **Care coordination:** Academic centers and community oncologist should collaborate to enable treatment to be administrated at the local communities rather than require patients to travel to tertiary academic centers to access clinical trials. Major academic centers should commit to support the scientific education and participation of community oncologist in clinical trials, clinical practices in this new era of 21st century immunotherapy.

5. **Ability to measure outcomes and cost:** EMR vendors should commit to enable the free flow of clinical information to enable real-time measurement of outcomes and cost. Payors should establish innovative payment models to pay for value and outcomes rather than procedures.

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Photo Gallery First Inaugural Breakthrough Summit 2015

Dr. Soon-Shiong and Dr. Sanjay Gupta Opening Remarks

Breakthroughs in Medicine & Technology Summit 2015

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Dr. Soon-Shiong & President Bill Clinton

Daniel Hilferty CEO Independence Blue Cross, Kathryn Davies Executive Director at NHS Wales, Jim Huffman SVP Health & Wellness Bank of America

Breakthroughs in Medicine & Technology Summit 2015

Sir Andrew Witty, CEO GlaxoSmithKline

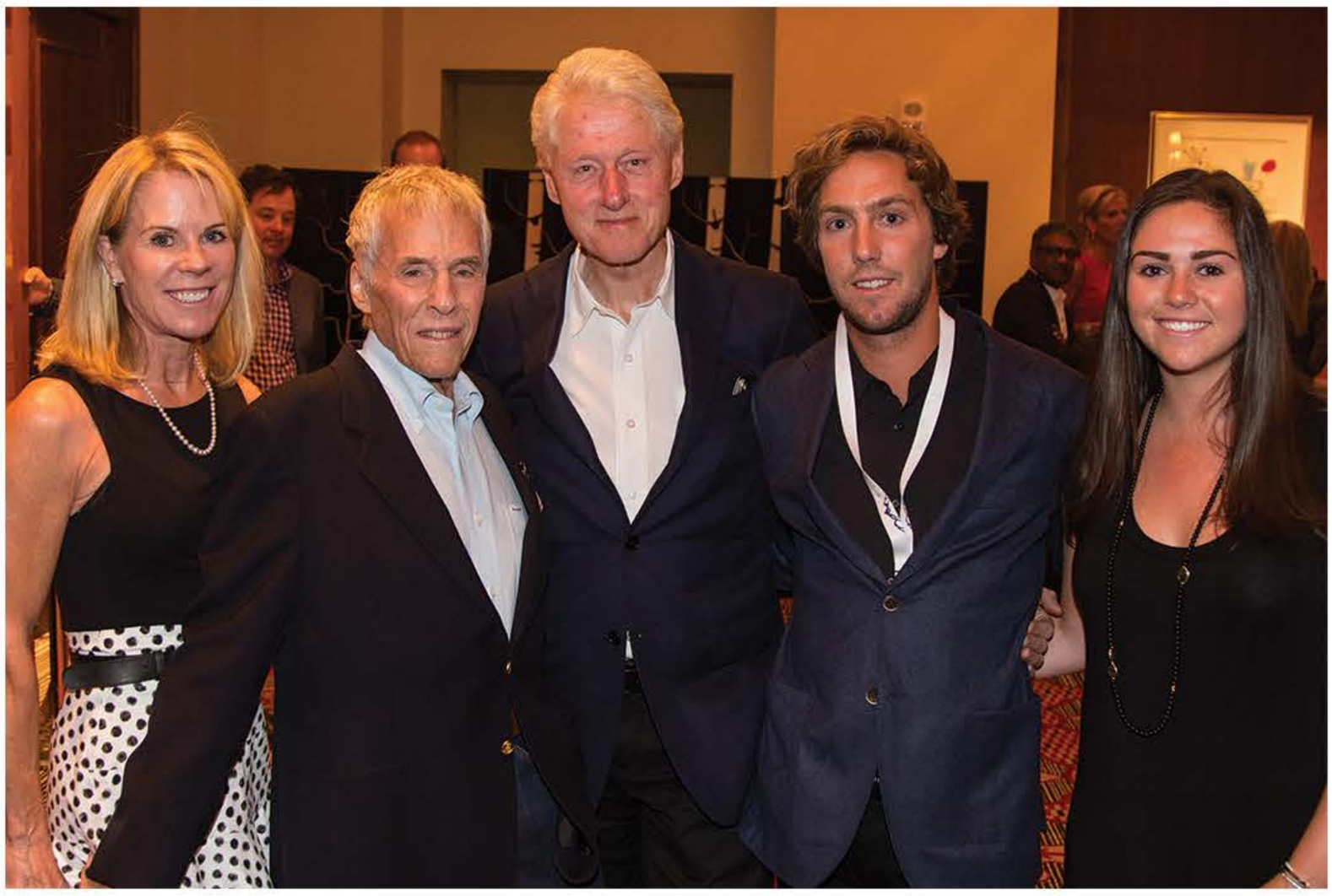
Bob Bradway CEO Amgen, Robert Hugin Chairman Celgene,
Simon Stevens CEO NHS England, Sir Andrew Witty CEO GlaxoSmithKline

Fly Fishing - Afternoon Activity at Jackson Hole

Fireside Chat with President Bill Clinton

Fireside Chat

Breakthroughs in Medicine & Technology Summit 2015



Burt Bacharach & Family

Dr. Sanjay Gupta

Fireside Chat with John Brennan CIA Director and
Steve Forbes Chairman Forbes Media

Bob Bradway CEO Amgen,
Christian Bréchot CEO Pasteur Institut,
John Chen CEO Blackberry